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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,205	02/15/2005	Michael Cahill	26418U	6456

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EXAMINER	
GEMENIANO, MALOU C	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/511,205	CAHILL ET AL.	
	Examiner	Art Unit	
	Malou C. Gemeniano	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *24-51* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 24, 25-41, drawn to a method for prevention or treatment of tumors of prostatic carcinomas and the pharmaceutical composition which influences the expression or function of proteins synthesized or secreted by tumors

Group 2, claim(s) 25, 45- 51, drawn to for diagnosing unspecified disorders associated with tumors.

Group 3, claim(s) 42-43, drawn to kit comprising at least one substance for detecting expression or function of proteins synthesized or secreted by unspecified tumors

If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

The inventions listed as Groups I-6 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature of Group I is a method for prevention or treatment of tumors of prostatic carcinomas and the pharmaceutical agent which influences the expression of function of proteins synthesized or secreted by tumors.

Groups II-III are drawn to a distinct method and distinct product that do not share the same inventive concept with each other as well as the products of Group I. The claimed inventions of Groups II-III recite unspecified materials and/or method steps that broadly

encompasses a number of active ingredients and proteins that are structurally, biologically and chemically divergent whereby they no longer share a special technical feature with the invention of Group I. The claimed inventions of Groups II-III recite materials and/or method steps that do not require the particulars or materials of the claimed treatment and pharmaceutical agent of (Group I), and thus have their own technical features, e.g. drawn to diagnosing unspecified disorder associated with tumors with unspecified substances (Group II), and drawn to a kit comprising at least one substance for detecting expression or function of proteins synthesized or secreted by tumors (Group III). Further, each of the groups has a technical feature not disclosed to be required for the other groups. For example, drawn to a pharmaceutical composition and a treatment of Group I is disclosed to be required for the diagnostic kit of Group III. The Groups are also distinct inventions because the method inventions can be performed using other and materially distinct products other than the diagnostic kit. In addition, since the pharmaceutical compositions and the substances used in each of the method claims are unspecified such that they encompasses molecules, proteins, polynucleotides that are so divergent and functionally distinct entities whereby their scope do not overlap and as such, the searches for these inventions are not overlapping and co-extensive, it would be a search burden to examine these patentably distinct inventions together. Furthermore, because these methods have such divergent purposes and functions as well as effects, the search for one method would not be co-extensive with another method. For reasons stated above and because these inventions do not share a common technical feature, restriction as indicated is proper.

Each invention is directed to a distinct goal, which comprises the use of separate products or methods in order to achieve its respective and intended objective. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups I to III do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features for the reasons set forth above.

In addition, this application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Applicant is required to further elect from the following species of substance or active ingredient as recited in claims 28-31, 35-37, 39-41, 47-49: (a) polynucleotide (b) peptide (c) small molecular compound.

Applicant is required to further elect from the following mode of administration of the active ingredient as recited in claims 33 and 51: (d) orally (e) intravenously (f) topically (g) inhalation.

Applicant is required to further elect form the following target of the active ingredient as recited in claims 28, 38-40, and 46: (h) activators (i) inhibitors (j) regulators (k) biological precursors

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: Claims 29-31, 28-31, 35-37, 39-41, 47-49 and claims dependent therefrom correspond to all species list above.

The following claim(s) are generic: claim 24, 25, 42

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Species (a)-(c) are drawn to patentably distinct inventions since they are drawn to molecules that are structurally and biologically distinct. Utilization of one type would be distinct from another type. For example, Proteins, which are composed of amino acids, polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules. In

addition small molecules embraces a wide variety of entities such that each of these entities do not share a common technical feature with each other nor with the polynucleotide or polypeptide. Therefore, species (a)-(c) are drawn to distinct invention Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Thus, it would be unduly burdensome for the examiner to search all the claimed inventions being sought in the pending claims.

Similarly, species of administration (d)-(g) are drawn to patentably distinct inventions since they are drawn to distinct mode of administration and therefore distinct modes of action. Each mode has a distinct target area or tissue. For example, oral administration is directed toward the mouth, intravenous administration is directed toward a vein or artery, topical administration is directed toward the skin and inhalation is directed toward a route via the nose. Each mode has a different function such as the route of entry and different objective as the target tissues are different among the different route. For reasons state above, these inventions do not share a common technical feature and restriction as indicated is proper.

Lastly, the species of target molecule for the active ingredient (h)-(k) are drawn to patentable distinct inventions since they are drawn to distinct target molecules that have very distinct functions. For example, activators' mode of action is to activate other molecules, inhibitors' mode of action is to inhibit other molecules, regulators' mode of action is to regulate other molecules and biological precursors mode of action is to generate non-precursor derivatives. Each of these molecules has distinct functions and mode of action and therefore, these species are considered patentably distinct. For reasons stated above, these inventions do not share a common technical feature and restriction as indicated is proper.

Applicant is advised that the reply for this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malou C. Gemeniano whose telephone number is 571-272-6451. The examiner can normally be reached on 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).
Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Dianiece Jacobs, whose telephone number is (571)-272-0532.
For all other customer support, please call the USPTO Call Center (UCC) at (800)-786-9199.

Malou C. Gemeniano, Ph.D
Examiner, USPTO, AU 1632

DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER